PT. SINKO PRIMA ALLOY

Alamat : Jl. Tambak Osowilangun Permai No. 61,
Pergudangan Osowilangun Permai Blok E7-E8,
Surabaya-Indonesia (60191)

Telepon : 031-7482816

Fax. : 031-7482815

Aftersale (WA) : 0821-4281-7085

Email : sinkoprima@gmail.com

Website : www.emiindo.id

SPA-BM/PROD-193. 25 Maret 2025. Rev03

Preface

Please read the User Manual carefully before using this product. The operating procedures specified in this User Manual should be followed strictly. This manual describes in detail the operation steps which must be noted, the procedures which may result in abnormality, and possible damage to the product or users. Refer to following chapters for details. Failed to follow the User Manual may cause measuring abnormality, device damage or personal injury. The manufacturer is NOT responsible for the safety, reliability and performance issues of such results due to user's negligence of this manual for using, maintenance or storage. The free services and repairs do not cover such faults either.

⚠ **Attention: Please read the User Manual carefully before using this product.**

For product upgrade, the device you received may not exactly in keeping with the description in this user manual, and we sincerely apologize for that.

Precautions

Please consider the security and validity before putting the product into use:

- Safety classification: type BF
- Measurement results should be explained by professional doctor combined with clinical symptoms.
- The reliability of this product depends on whether the operator's operation is in accordance with the operating and maintenance instructions of this manual.
- The intended operator may be the patient.
- No maintenance or repair during device using.

⚠ **Warning: Replacement of accessories that are not supplied by our company may result in errors. Any maintenance personnel who has not been trained by our company or other authorized service organization should not attempt to maintain the product.**

Responsibility of the user

- The user should read this user manual carefully before operating, and operate it in accordance with the manual.
- Although the device has been designed with a view to safety requirement enough, the user should not neglect the state of the equipment and patient observation.
- The user is responsible to supply the use situations of device to our company.

Responsibility of Our Company

- Our company supplies the qualified product to the user in accordance with enterprise standard.
- Our company performs device repair in warranty period (a year) and maintenance after warranty period.

- Our company responds promptly to the user's request.
- Upon request, our company may provide, with compensation, necessary circuit diagrams, calibration instructions and other information to help qualified technician to maintain and repair some parts, which our company may define as user serviceable.
- Our company is responsible for safety, reliability, and performance of device only in the conditions that:

All installation, expansion, debugging, change, repair of this device are conducted by our qualified personnel; and,

Applied electrical appliance is in compliance with relevant requirements, and the device is operated under strict observance of this manual.

Statement

Our company owns all rights to this unpublished work and intends to maintain it as confidential information. This user manual is used only for reference of operation, maintenance, or repair of our device. No part of this can be disseminated to others. Our company will not be responsible for all consequences and liabilities arising from the use of this user manual for other purpose.

All information contained in this user manual is believed to be correct. Our company shall not be liable for incidental and consequential damages in connection with the furnishing, performance, or use of this material. This user manual may refer to information and protected by copyrights or patents and does not convey any license under the patent rights of our company, nor the rights of others. Our company does not assume any liability for arising out of any infringements of patents or other rights of the third parties.

Our company owns the final explanation right to this user manual. And our company reserves the right to change the content of this manual and technology and to modify product specification without prior notice.

Contents

Chapter 1 General

1.1 Safety precautions

- **Before use, please read the "Safety Precautions" carefully in order to correctly use the device.**
- **Since professional training is unnecessary. Operator should use the device after fully understand the requirements in this user manual.**
- **To prevent users from being hurt or property loss due to improper use, please read the "Safety Precautions" and use this product properly.**

For safety reasons, please do obey the safety Precautions.

⚠ ATTENTION ⚠

Improper use may result in personal injury or property damage.

Property damage is related to the damage of housing, family property, livestock and pets.

⚠ CONTRAINDICATION ⚠

No.

⚠ WARNING ⚠

- NIBP measurement must not be performed on patients with sickle-cell disease or under any condition which the skin is damaged or expected to be damaged.
- For patients with severe coagulation disorders, the implementation of automatic blood pressure measurement shall be determined according to their clinical evaluation, because the rubbing between limbs and cuff may result in a danger of hematoma.
- For severe blood circulation disorder or arrhythmia patients, please use the device under the guidance of a doctor. Otherwise it may lead to acute internal hemorrhage, or measurement error as a result of squeezed arm.
- Patient who is pregnant or has preeclampsia should use the device under the guidance of a doctor.

Measurement Limitation

The oscillometry method has some limitations depending on the patient's condition. This measure is based on the regular pulse wave generated by arterial pressure. In the case where the patient condition makes such a detection method difficult, the measured value becomes unreliable and the measuring time increases. The user should be aware that the following conditions will make the measurement unreliable or measurement time extended. In this case, the patient's condition will make the measurement impossible:

Patient Movement

Measurement will be unreliable or may be impossible if the patient is moving, shivering or having convulsions. As these conditions may interfere the detection of the arterial pressure pulsation, and the measurement time will be prolonged.

Cardiac Arrhythmia

Measurement will be unreliable and may be impossible if the patient has irregular heartbeat arisen from cardiac arrhythmia, and the measurement time will be prolonged.

Heart-lung Machine

Measurements will not be possible if the patient is connected to a heart-lung machine.

Pressure Change

Measurement will be unreliable and may be impossible if the patient's blood pressure is changing rapidly over the period of time during which the arterial pressure pulsation are being analyzed to obtain the measurement values.

Severe Shock

If the patient is in severe shock or hypothermia, measurement will be unreliable since the decrease of the blood flowed to the peripheries will cause the reduction of artery pulsation.

Heart Rate Extremes

Measurements cannot be made at a heart rate of less than 40 beats/min or higher than 240 beats/min.

Obesity Patient

The thick fat layer under the limb will decrease the measurement accuracy, as the vibration from artery cannot arrive to the cuff, which is arisen from the fat damping.

⚠ **ATTENTION** ⚠

- Please use the device under the environment with proper temperature and humidity (refer to the specification), otherwise the result may be inaccurate.
- Repeated measurements may lead to congestion in the arm, continue to measure may not obtain correct blood pressure, please wait until the blood circulation of arm is normal.
- Prolonged repetitive measurement may cause purpura, ischemia and nerve injury in the limb wearing the cuff.
- Do not apply cuff on the site where intravascular treatment is being performed or with catheter connection, otherwise it may cause temporary blockage of blood flow and then cause injury to the patient.
- Do not take measurements on the side with mastectomy or lymph node dissection.
- The pressure by cuff may cause temporary weakness of some function of the body. So do not use monitoring medical electrical equipment on corresponding arm.
- Avoid any movement during measuring, because it may delay the blood circulation of patient.
- The device needs 2 hours to recover from the lowest storage temperature to reach its performance of intended use.
- The device needs 4 hours to recover from the highest storage temperature to reach its performance of intended use.

- The minimum value of the patient's physiological signal is the lowest limit that the device could measure. The measured result may inaccurate if the device running below the minimum amplitude or minimum value of patient's physiological signal.

The BP value measured in the following situations may be different:

- After eating (within 1 h), or having drinks containing alcohol, caffeine or black tea;
- After smoking, taking exercises or bathing;
- Talk or body move during measurement;
- Patient is nervous, excited or in unstable emotion;
- Adopts wrong posture, such as bend down (lean forward) or cross legs;
- A sharp increase/decrease in room temperature, or measurement temperature changes constantly;
- Measured on a moving vehicle;
- Long term continuous measurement.

⚠ ATTENTION ⚠

- Self-diagnosis and treatment by measure results may be dangerous. Please follow the instructions of your physician, and hand measure result to the doctor who knows your health state for diagnosis.
- For the person who can't express oneself, please use the device under the guidance of a doctor.
- Otherwise it may cause accident or dissension.
- The device is not intended for use for other purpose except NIBP measurement, otherwise it may result in accident or malfunction.
- Do not leave the cuff under over-inflated state for long time, otherwise it may cause risk.
- Possible explosion hazard if used in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.
- The disposal of the packing material should follow the applicable waste control regulations and keep it out of children's reach. Otherwise it may cause harm to the environment or children.
- Please use specified accessories and verify if the device and accessories work safely and normally before use. If not, the measurement result may be inaccurate or cause accident.
- If the device gets damp accidentally, it should be placed in a dry and ventilated place for a period of time to dissipate moisture. Otherwise the device may be damaged due to moisture.
- The device should be stored or transported under the specified environment condition to avoid measurement error.

- It is recommended to regularly check if there is any damage on the device or accessories, if there is, stop using it and contact the biomedical engineer of hospital or our representative institution.
- Do not disassemble, repair or modify the device without permission, otherwise the measurement will be inaccurate.
- Measurement error may occur if the device is used on a moving platform.
- Possible falling risk if the device is placed on a tilted surface.
- Dispose of packing materials, waste batteries and end-of-life products in accordance with local laws and regulations. User should perform proper treatment to the waste products and materials according to the regulations.
- Replacement of accessories that are not supplied by our company or other authorized service organization should not attempt to maintain the product.
- The device can only be used for one patient at a time.
- If the small parts on the device on the device are inhaled or swallowed, please consult a doctor immediately.
- The device and accessories are processed with allergenic material. If you are allergic to it, stop using this product.
- Do not touch the printer and operator while using the device.

⚠ **ATTENTION** ⚠

All analog and digital equipment connected to this device must be certified to IEC standards (such as IEC60950: Information technology equipment-Safety and IEC60601-1: Medical electrical equipment-Safety), and all equipment should be connected to in accordance with the requirement of valid version of the IEC60601-1-1 system standard. The person connecting the additional equipment to the signal input and output port is responsible for whether the system complies with the IEC60601-1 standard.

The software is developed in accordance with IEC6060-1-4. The possibility of risks arising from errors in the software program has been minimized.

The device shall comply with the standard IEC 80601-2-30: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers.

1.2 Functional description:

The device is applicable for adults for NIBP measurements. There is no need to manually wear the cuff, user could take the measurement only by himself.

Suitable arm circumference: 17 cm ~ 42 cm.

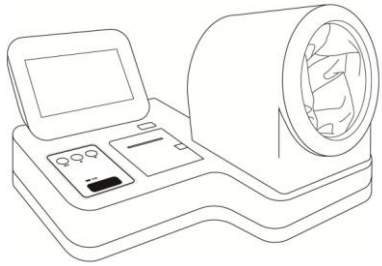
Printing of measurement result is supported.

The device can be widely used in hospitals and various medical institutions.

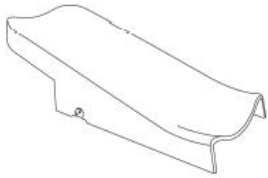
Chapter 2 Product Structure

2.1 Accessories

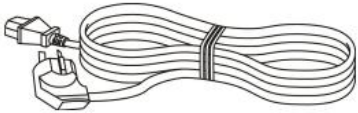
The package contains all accessories, open it and check.



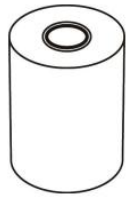
Main unit



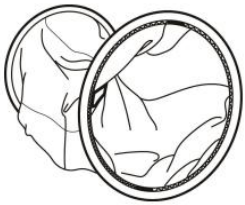
Hand rest



Power Cable



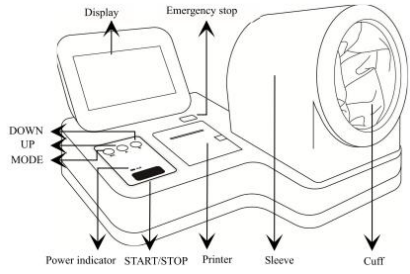
Print Paper



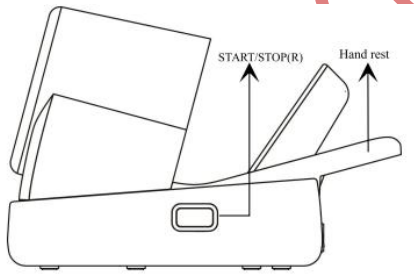
Cuff (installed on the device)

2.2 Description of each part

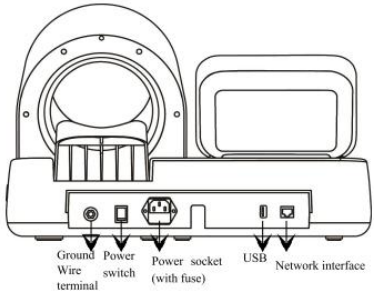
Front view



Right side view



Rear View



⚠ **ATTENTION** ⚠

Equipotential terminal: when the potential is used together with other equipment, connect other equipment to the equipotential terminal of the device by a cable, in order to eliminate the ground potential difference between different device to ensure safety.

Fuse T3.15AH250V

Replacement of fuse: unplug the power cord, gently open the fuse slot by tools, and replace the fuse.

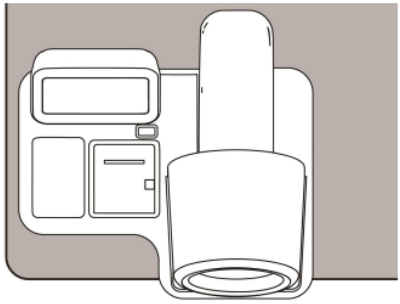
The primary protection of the device is realized by power plugs grounding method, which is included in room protective grounding system. One end of the equipotential grounding wire (potential equalization wire) is connected to the equipotential terminal on the rear panel of the device and the other end is connected to a connector of the equipotential system. If the protective grounding system is damaged, the equipotential grounding system undertakes the safety function for protecting the grounding wire. Before each use, check whether the device is in good working condition.

At the end of the service life, the product described in this manual, as well as its accessories, must be disposed in compliance with relative disposal regulations. If you have questions concerning disposal of the product, please contact us.

Chapter 3 Installation

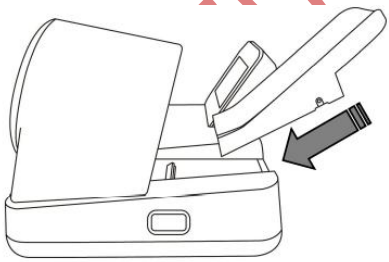
3.1 Placement of main unit

Place the main unit at the corner of table.



3.2 Install hand rest

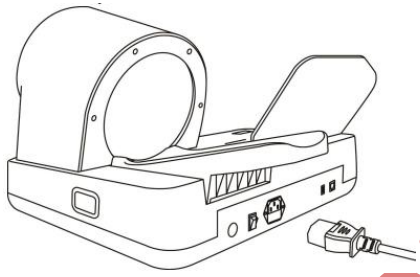
Insert the hand rest into the slot behind the sleeve.



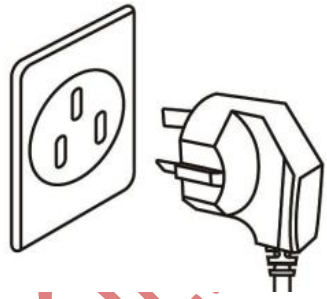
Press down the hand rest until to the positioning hole.

3.3 Connect with power

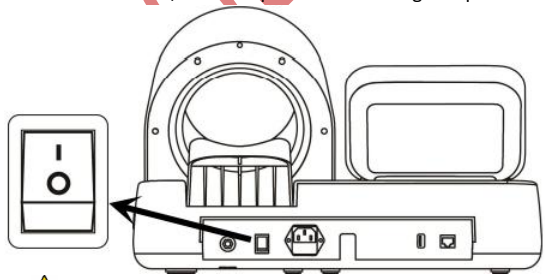
Insert the power cable to the power socket on the back of the device.



Insert another end into the mains socket.



Turn the power switch to “ON”, then the power indicator lights up.



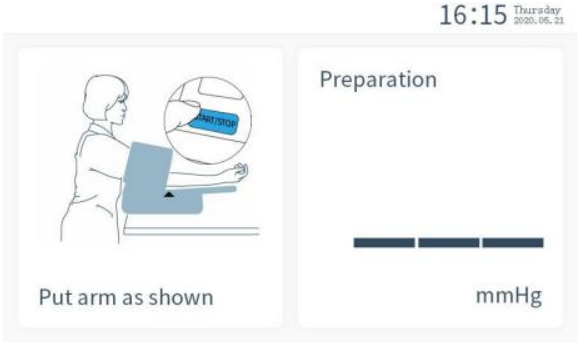
⚠ WARNING ⚠

To avoid electric shock hazard, the device must be connected to a protective grounded supply main.

⚠ ATTENTION ⚠

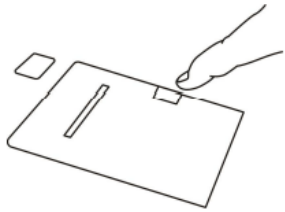
After turning the power switch to “ON” state, if the power indicator does not light up, or the deice smokes or smells, immediately cut off the power, do not use the device and contact our company for repair.

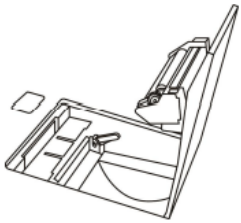
After turning the power switch to “ON” state, if there is no display on the screen, or blurred screen or white screen appears, please contact our company for repair.
The device is turned on, after initializing, it enters pre-test interface.



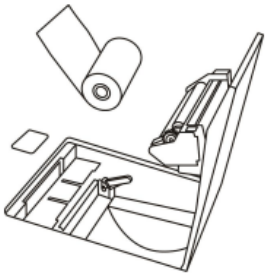
3.4 Install print paper

Press the button on paper compartment cover to open it.

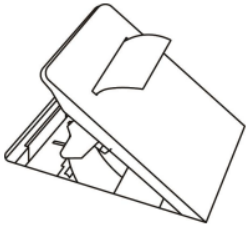


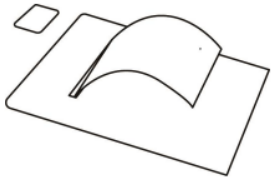


Install a paper roll into the compartment.



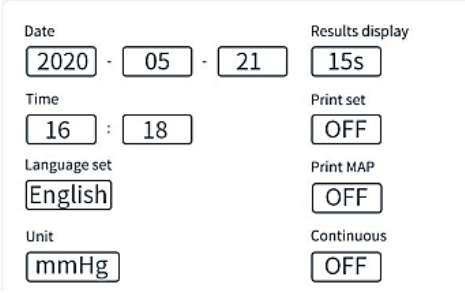
Pull out the paper from the exit on the compartment cover for about 5cm, and press the cover to close it.





Chapter 4 Setting

In the pre-test interface, press and hold “MODE” button, then press “START/STOP” button for about 3s, the device enters menu setting interface.



4.1 Change Settings

In the setting interface, press “MODE” button to select the item to be changed, the items include Date, Time, Language set, Unit, Result display, Print set, Print MAP, and Continuous.

Press UP and Down button to change the content of the item.

Press “MODE” button to move the next item.

After all items are set, press and hold “MODE” button, then press “START/STOP” button for about 3s to exit.

4.2 Content of Settings

No.	Settings		Contents	Function description
1	Date	year	2020 ~ 2037	Setting of displayed date and time
2		month	01 ~ 12	
3		day	01~31	
4	Time	hour	00~23	
5		minute	00~59	
6	Language set		English/Chinese	Set display language
7	Unit		mmHg. kPa	Display unit of pressure
8	Results display		OFF/15 s/30 s	The displaying time length of measured result

9	Print set	ON/OFF	Whether to turn on the print function
10	Print MAP	ON/OFF	Whether to print the average blood pressure
11	Continuous	OFF/ON1/ON2	OFF: turn off continuous measurementfunction; ON1: turn on continuous measurementfunction, measurement interval is 30s; ON2: turn on continuous measurement function, measurement interval is 60s.

⚠ **ATTENTION** ⚠

In setting interface, pressing “START/STOP” button is unable to start/stop the measurement.

If the displayed time is set, after restart the device, the time should continue to run according to the set time. Otherwise, the backup battery (CR2032) inside the device must be replaced, please contact our company for details.

5 Measurement

⚠ ATTENTION ⚠

The device is only applicable for adults, children or patient of arm circumference beyond the range of 17 cm ~ 42 cm cannot use the device.

Do not use any mobile instrument near the device, such as cell phone.

Patient should not talk or move during measuring, and avoid muscle activities. Do not touch the cuff or sleeve when measuring.

The measurement can be taken on either arm. When measuring on the left arm, user could use the “START/STOP” button on the right side of the device to operate.

It is recommended to take 5 minutes’ rest at least before measurement.

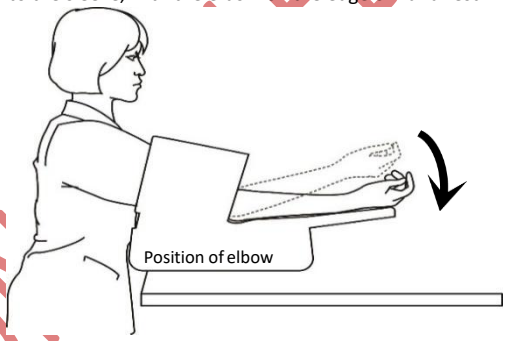
5.1 Adjusting of posture and arm

Patient should have bare arm or only thin clothing;

Adopt comfortable sitting posture, put your feet flat on the floor, and do not cross legs.

Relax and sit upright, adjust the seat height to make sure the center of sleeve stays the same level with patient’s heart;

Put the arm into the sleeve, with the elbow on the edge of hand rest.



5.2 Measure

After adjusting to the correct position, press “START/STOP” button, the device automatically starts measuring.

If continuous measurement function is turned on, the device will prompt current number of measurements and real-time pressure value on the screen.

After the measurement is finished, measured results are displayed on the screen.

If continuous measurement function is turned on, after all measurements are completed, the device displays the average value of measured result. If not, it displays the count down before starting the next measurement. After countdown is finished, the device automatically starts the next measurement. During the waiting period, user could press “START/STOP” button to start the measurement.

In continuous measurement process, if the difference of measured result between the first and second measurement is larger than 5 mmHg, the device will automatically start measuring for the third time.

If “Print set” is set to on state, after the measurement is completed, measured result will be printed automatically.

5.3 End of measurement

After the measurement id finished, wait a few seconds, the cuff will automatically release, then take out your arm from the sleeve.

5.4 Stop measuring

If you feel pain in the arm during measuring, or other abnormal circumstance occurs, immediately press the “START/STOP” button to cancel the measurement.

5.5 Emergency stop

If the measurement cannot be canceled after pressing “START/STOP” button, immediately press the “Emergency stop” button, and take out your arm from the sleeve.

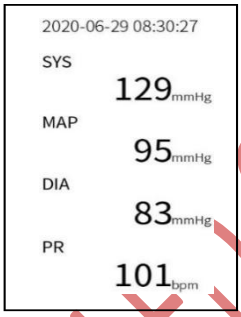
Make sure the device and personal are safe, and press the “Emergency stop” button again to release it, the device enters pre-test state.

The measurement can be affected by many factors, if the device prompts error message on the screen, repeat the measurement after removing the causes.

Chapter 6 Printing

In setting interface, if “Print set” is set to on state, after the measurement is completed, measured result will be printed automatically. If the device is in continuous measurement mode, measured result will be printed after all measurement are completed.

In setting interface, if “Print MAP” is set to on state, the result printed will contain the average value of blood pressure.



Measurement result printed

⚠ ATTENTION ⚠

Do not block the paper exit.

The printer can automatically cut the paper after printing, do not pull paper with force.

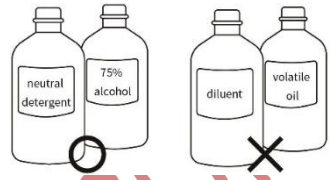
Do not open the printer compartment or replace print paper during measuring.

Do not touch the internal of printer by hand.

Chapter 7 Cleaning and Maintenance

Please obey the precautions and correct operation method in the user manual, otherwise, our company will not responsible for any quality issues.

⚠ WARNING ⚠



Cut off the power before cleaning.
Maintenance or repair is not allowed during device using.
Do not let water enter the main unit.
Do not use volatile oil, diluent or gasoline to wipe the device.

⚠ CAUTION ⚠

High pressure sterilization to the device is forbidden.
Do not let water or cleaning liquid enter the device to avoid damage.
Do not soak the device into liquid.
Of the device shows any sign of damage or deterioration, do not use it.

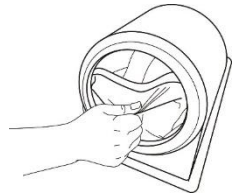
7.1 Maintenance of Cuff

If the cuff gets dirty, take it down from the sleeve for cleaning.

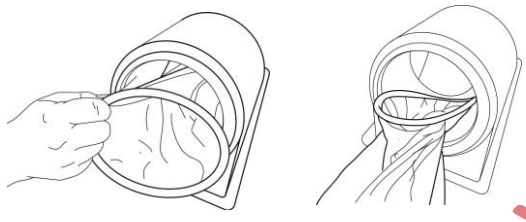
7.1.1 Remove cuff

Pull out the rear locating ring of the cuff from the slot at the back of the sleeve.

Pull out the front locating ring of cuff from the slot at the front of the sleeve.

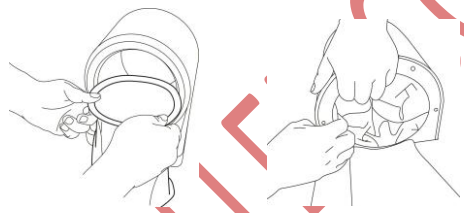


Remove the cuff from the sleeve.

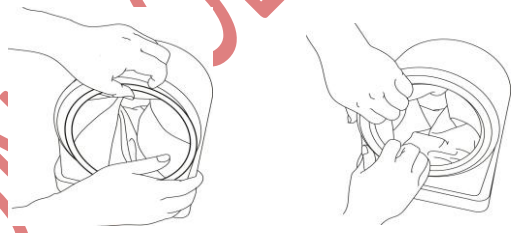


7.1.2 Install cuff

Put the cuff in the sleeve from the front side, pull out the rear locating ring at the back of the sleeve and insert it into the slot.



Insert the front locating ring into the slot on the sleeve.



⚠ **ATTENTION** ⚠

Do not twist the cuff when installing it.

7.2 maintenance of main unit

It is recommended to clean the device once a month. If it dirty, wipe it with a soft, dry cloth.

If it gets very dirty, it its available to dip the soft cloth into water or mind detergent, and wring it out, then use the cloth for cleaning.

7.3 Calibration

The device should be inspected and calibrated per year (or obey the requirements of the hospital). Calibration can be performed in the state specified inspection institution or by professional personal, or you can contact our company.

The device has static pressure test mode for testing by technical department, contact our company for details.

There is a calibration interface on the rear of device. It is in closed state during normal using, and do not open it in non-calibration conditions. After using the interface, please restore it to close state to ensure normal working.

⚠ **SUGGESTION** ⚠

- Do not expose the device in direct sunlight for long time, otherwise the display may be damage.
- The basic performance and safety of the device are not affected by dust or cotton wool in normal environment, while the device shall not be placed where with high temperature, humidity or plenty of dust.
- To avoid device damage, keep the device out the reach of children and pets.
- Avoid the device close to extreme high temperature such as fireplace, otherwise the device performance may be affected.
- Do not store the device with chemical medicine or corrosive gas.
- Do not place the device where there is water.,
- Do not place the device where with slope, vibration, or impact.

Chapter 8 Specification

Model		BPM PRO
Voltage		100 ~ 240V, 50/60 Hz
Power		± 6W-10W
Display		Color LCD display 6.75”
Measurement range		0 ~ 297 mmHg
Resolution		1 mmHg
Accuracy		Static pressure: ± 3 mmHg
Protection		IPX0
Weight		5.6 kg
Dimention		460(P) x 450(L) x 300(T) mm
Operating condition	Temperature	5°C ~ 40°C
	Humidity	15% ~ 85% RH
	Atmospheric pressure	700 ~ 1060 hPa
Transport and storage	Temperature	-20°C ~ 55°C
	Humidity	≤95% RH
	Atmospheric pressure	700 ~ 1060 hPa

Chapter 9 Error Message

Error message		Possible Causes	Solution
Message	Code		
Error and restart	Er6	Arm position is incorrect; Patient's arm is too thin;	Remove the errors and measure again: • Ensure the arm is in correct position; • Suitable arm circumference is 17 cm~42 cm; • Do not move during measuring; • The device will deflate automatically if pressure exceeding the upper limit, and cancel the measurement. • Confirm whether the pulse wave exceeds measurement range.
	Er8	Atmospheric pressure error. Valve can not be opened.	
	Er9	Weak signals. The pulse of measured object is too weak or cuff is wrapped too loose. Arm position is incorrect;	
	Er10	Out of limit. The measured BP value exceeds normal measurement range.	
	Er11	Excesive movement. When measuring, the signal contains motions artifacts or too much interference.	
	Er12	Overpressure. Cuff pressure exceeds normal range : 300 mmHg	
	Er13	Saturated signal. Movements or other factors lead to too big signal amplitude.	
	Er19	Timeout. Over 3 mins (180 s) when cuff pressure is 2 kPa (15 mmHg)	
Instrument Failure	Er2	Self-test failure. Sensor or A/D sampling error.	Contact our company for repair
	Er7	Air leakage. Air leakage in the valve or airway.	
	Er14	Air leakage. There is leakage in the system.	
	Er15	System failure. There is something wrong with air pump, A/D sampling, pressure sensor or the software after turning on the device	

	Er20 Er21 Er22 Er23 Er24 Er25 Er26 Er27	Device failure	
Emergency Stop		“Emergency stop” button is pressed.	Make sure the device and personal are safe, and press the “Emergency stop” button again to reset it, the device enters pre-test state.
Printer out of paper		Out of paper or paper jam	Re-install the print paper.
Printer compartment on		Printer compartment is open.	Close well the printer compartment
Cutter abnormal		Paper cutter failure.	Restart the device, if the error message still appears, please do not use the printer, and contact our company for repair.

Chapter 10 Troubleshooting

Abnormal	Possible reason	Solution
There is no display on the screen after turning on the power	• Power cord is not well connected • Fuse is damaged.	• Make sure the power cord is well connected
The device does not measure after pressing "START/STOP" button.	• The device does not enter pre-test interface before pressing.	• Operate the device to enter pre-test interface
The measured blood pressure value is extreme high/low	• Arm position is wrong. • Patient move during measuring. • Patient has an irregular pulse wave.	• The elbow should be placed at the edge of the hand rest. • Do not move during measuring. • Find regular pulse wave by auscultator method.
Abnormal measurement result	• Patient is under abnormal condition • Arm position is wrong. • Patient moves during measuring • Patient has an irregular pulse wave • The sleeve center and patient heart are not on the same level.	• Confirm whether patient's condition will affect the measurement of blood pressure. • The elbow should be played the edge of hand rest. • Do not move during measuring. • Find regular pulse wave by auscultator method. • Adjust the seat height to make sure the center of sleeve stays the same level with patient's heart
Unable to print	• Print paper is not correctly installed • Paper jam occurs	• Install the print paper correctly • Open the printer compartment, re-install the paper.

⚠ SUGGESTION ⚠

If problems are not solved after processing the methods according to above table, please contact us for maintenance.

Chapter 11 Symbol

Symbol	Mean	Symbol	Mean
	Warning! Please refer to the accompanying document (the user manual).		Refer to instruction manual/ booklet
	Serial number		Type BF applied part
	Network interface		USB interface
	“OFF” (power)		Manufacturer
	"ON" (power)		This way up
	Equipotentiality		Stacking limit
	Fragile, handle with care		Atmospheric pressure limitation
	Keep dry		Temperature limitation
	Humidity limitation		Paper exit
	Recyclable	CE 0123	CE mark, it indicates that this product comply with the EU directive for medical devices 93/42/EEC
	Waste disposal mark, this symbol indicates that the waste of electrical and electronic equipment can not be disposed as an unclassified municipal wasteand must be recovered separately.		

Note: Your device may not have all symbols above.

BLOOD PRESSURE MONITOR

BPM PRO

MANUAL BOOK